STATE OF CALIFORNIA
DEPARTMENT OF CONSUMER AFFAIRS

STATE AND CONSUMER SERVICES AGENCY • ARNOLD SCHWARZENEGGER, GOVERNOR

**MEDICAL BOARD OF CALIFORNIA**
1434 Howe Avenue, Suite 92, Sacramento, CA 95825
(916) 263-2389 Fax (916) 263-2387 www.mbc.ca.gov

Medical Board of California
and
Board of Registered Nursing

Forum on
Public Safety and the Use of Lasers
for Cosmetic Procedures
(Business & Professions Code
Section 2023.5)

August 30, 2007
Holiday Inn
2726 S. Grand Avenue
Santa Ana, CA 92705
714-481-6300 or 714-966-1889

***Project Staff:***

*Medical Board of California:*
*Janie Cordray*
*(916) 263-2389*
*jcordray@mbc.ca.gov*

*Board of Registered Nursing:*
*Janette Wackerly*
*(916) 322-3350*
*Janette_Wackerly@dca.ca.gov*

# AGENDA

9:00 a.m – 1:00 p.m.

1. **Welcome - Introductions**

2. **Overview of Charge - Business & Professions Code Section 2023.5**

3. **Statement of Purpose of the Meetings - Public Health & Safety**

4. **Testimony***

   - Representatives of the Laser Industry
   - Representatives of the Nursing Associations
   - Representatives from Physician Assistant Organizations
   - Representatives from Physician Organizations
   - Consumers

* The Committee invites comments, especially relating to the following:
  - Patient safety
  - Patient harm: What are the complications experienced and what are their causes?
  - Training and education: Should there be additional certification or educational requirements for the use of new technology?
  - Physician supervision: What minimum supervision is needed? Who must provide examination, and what is the standard of care to ensure patient safety?
  - Aftercare and follow-up: Who is responsible and what is the standard of care to ensure patient safety?
  - Patient referrals and aggressive advertising techniques: To what extent does illegal patient referrals and aggressive advertising play in misleading the public?
  - Misrepresentation of personnel's credentials
  - Other practices or issues that may mislead consumers
  - Public awareness and patient expectations: Are patients aware of the risks prior to undergoing treatment? Do patients have fully informed, realistic expectations?
  - Liability: Who is liable and how are patients to know?
  - Technological trends and other issues related to patient safety
  - Business trends that may impact patient safety
  - Need for changes to current law, regulation, and enforcement

**5. Issues for discussion at future meetings**, to be held September 13 in Sacramento and October 31 in San Diego

**6. Public Comment**

**7. Adjournment**

| |
|---|
| ***The mission of the Medical Board of California is to protect healthcare consumers through the proper licensing and regulation of physicians and surgeons and certain allied healthcare professions and through the vigorous, objective enforcement of the Medical Practice Act.*** |
| ***NOTICE: The meeting is accessible to the physically disabled. A person who needs disability-related accommodations or modifications in order to participate in the meeting shall make a request to the Board no later than five working days before the meeting by contacting Rhonda Baldo at (916) 263-2600 or sending a written request to Ms. Baldo at the Medical Board of California, 1420 Howe Avenue, Suite 14, Sacramento, CA 95825. Requests for further information should be directed to the same address and telephone number.*** |
| ***Meetings of the Medical Board of California are open to the public except when specifically noticed otherwise in accordance with the Open Meetings Act. The audience will be given appropriate opportunities to comment on any issue presented in open session before the Board, but the Chair may apportion available time among those who wish to speak.*** <br> ********** <br> ***For additional information, contact Janie Cordray at (916) 263-2389.*** |

*Law Offices of*
NORMAN C. DAVIS

2677 North Main Street, Suite 930
Santa Ana, California 92705-6632
Telephone: (714) 835-1600
Facsimile: (714) 835-3227
E-mail: ndavis5317@aol.com

# MEDICAL PRACTICE REGULATIONS (CALIFORNIA)

(September 2007)

| | |
|---|---|
| B&P 650 | Referral inducement/ exception for FMV |
| B&P 651 | Advertising false and deceptive |
| B&P 2051 | Practice of medicine defined |
| B&P 2052 | Attempting or advertising to practice without license |
| B&P 2234 | MD aiding and abetting business in practice in violation |
| B&P 2264 | MD aiding and abetting unlicensed person to practice |
| B&P 2272 | Advertising practice in own name or appd Fict Name |
| B&P 2286 | MD aiding and abetting in violation of corp code |
| B&P 2408 | Shareholders officers of medical corporation licensed |
| B&P 2415 | Fict name permit reqd |
| B&P 2417 | MD providing services for business in violation of ins code |
| Corp Code 13401 | Prof corporation ownership/control |
| Corp Code 13403 | Prof corporation shareholders and directors |

# NURSING PRACTICE REGULATIONS

B&P 2700 – 2838 Nursing Practice Act

CA Code of Regs Title 16 1402-1493 Nursing Regulations

# Delegation of Procedural Authority - Understanding the Issues and Controversies

Aesthetic Taskforce Meeting

August 30, 2007

Irvine, CA

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Today the practice of medicine is seeing the following changes
  - Reimbursement going down
  - Overhead going up
  - Administrative workload going up
  - Physician workload going up
  - Incomes negativity impacted

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Major Remedies
  - Increase physician workload
  - Increase patient fees
  - Change care offered
    - Non-procedural medicine has its limits
  - Add new procedures
  - Add new procedures performed by staff

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Today the remedy chosen most often is the addition of procedures performed by staff (allied healthcare personnel)
- Those that are cash procedures
- Are primarily aesthetic
- The above occurrences have created a major "controversy"

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- This most often employed remedy – procedures delegated to staff personnel
  - Has caused pressure on and concerns from:
    - The regulatory organizations
    - The medical profession
    - The nursing profession
    - The cosmetology profession
    - The insurance industry
    - The medical device manufacturers
    - The patient

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- When contemplating the above remedy the following are impacted:
  - Practice economics (facility and personnel)
  - Regulations
  - Medical Malpractice Insurance

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Regulations – Something that the physician/provider didn't have to worry about before
- Now understanding them is critical if the practice/venture is to be successful and if the current controversy is going to be resolved

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Regulation
  - Federal – Food and Drug Administration
    - FDA - Bureau of Radiological Health (BRH)
      - Categorize all light-emitting devices by their output power or energy – Class I-IV
    - FDA – Office of Device Evaluation (ODE)
      - Categorize all medical devices – Class I-III
    - These two classification schemes are frequented confused, and can have an impact on who can use a device

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Regulation – FDA
  - All Class II medical devices (this includes most aesthetic devices) cleared by the FDA carry the following labeling:
    - Caution: Federal law restricts this device to sale by or on the order of a _____, the blank to be filled in with the work "physician", "dentist", "veterinarian", or with the descriptive designation of any other practitioner licensed by law of the state in which he/she practices to use or order the use of the device

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Regulation – FDA
  - Controls the manufacturer
    - To whom they may sell the product
      - Some states may further define this
    - What they may say regarding their cleared indications (labeling)
  - Controls the physician
    - Any marketing the physician would like to do regarding the procedures they are performing

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Regulation – FDA
  - All medical lasers and most other light-emitting devices (IPL's) are cleared by the FDA under the same section of the law – 878.4810, as a "Laser Instrument, Surgical, Powered"
  - Even though some of these devices are not described as invasive surgical products

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Regulation - State
  - State Legislature
    - Different factions trying legislatively to control the use of these devices
  - State Regulatory Boards
    - Boards of Medicine
    - Boards of Nursing
    - Boards of Cosmetology
    - Boards of Electrology
    - Radiation Control Boards

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Regulation - State
  - State Legislature
    - There has been many attempts in multiple states to pass bills for the control of aesthetic light-emitting device procedures
    - Most of these have been driven by various political agendas and have not always fared well
    - This is the most difficult and time consuming route
    - Few states have used this method
    - Most states have general statutes that give this authority to the various regulatory boards

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Regulation - State
  - State Regulatory Boards
    - Control who may use the device and under what conditions
    - This control may be in the form of a regulation, rule, or simply proposed as a policy or philosophy
    - Since many states only have a policy or philosophy there is much controversy regarding their official status

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Regulations – State
  - State Regulatory Boards
    - Many did not know it was their responsibility
    - Different boards in a given state can have different opinions as to who may use the device
    - Have no or little expertise on the subject
    - Have no or minimal resources to promulgate new regulations
    - Different groups within a given board may have opposing opinions

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Regulation - State
  - State Regulatory Boards
    - Determining who may use the device
      - May depend on the procedure
      - May depend of some type of training
      - May depend on type of licensure
      - May depend on type of supervision

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Current Market Conditions
  - Physicians are not generally performing these procedures
  - They are generally termed non-invasive procedures performed with an FDA Class II prescriptive device
  - They require an appropriate amount of training for all involved, and the current training is not adequate
  - Physician on-site presence has little effect on patient safety

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Since the majority of these systems are new to the market, many physicians, whatever their specialty, may not have received training on them during their formal medical education
- It appears that the majority of adverse events stem from inadequate training
- State regulatory boards want more control and better provider training
- Insurance companies are requiring more training

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- All stakeholders in this marketplace want access to the technology either as a provider or a recipient
- There is currently no common answer to 50 different state approaches
- The answer does involve all properly informed and involved participants determining what is appropriate for the patient not for just their stakeholder group

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- The answer does involve some combination of the following:
  - Appropriate control
    - Statute
    - Regulation/Rule (Board level)
  - Appropriate oversight – if the procedure is to be delegated
  - Appropriate training/education – this could be provided by multiple sources and lead to some type of official state certification
  - Determination of appropriate locations for providing the service

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- The Solution Process
  - Must lead to the "workable and enforceable" regulation
  - If not done properly
    - Will lead to a long drawn out process
    - May lead to lawsuits
      - Parties that have been providing these services for 7-8 years do not go away quietly
    - May lead to even less oversight
      - Could lead to less patient safety

# Delegation of Procedural Authority - Understanding the Issues and Controversies

- Remember
  - Since the medical community is asking for these devices to be designed and manufactured by industry
    - Really the first time medical devices are being designed and manufactured for use by other than a physician
  - Since the FDA only controls the manufacturer and not device use
  - The answer lies with the states
    - Legislature or regulatory boards
    - They must get the support and information they need from all appropriate sources
    - Today most are not

American Academy of Physician Assistants
950 North Washington Street ■ Alexandria, VA 22314-1552 ■ 703/836-2272 Fax 703/684-1924

# Physician Assistants and the Use of Laser Technology in Physician-Supervised Medical Practice

**Requirements of New California Law**

Senate Bill 1423 of 2006 requires the Medical Board of California, in conjunction with the Physician Assistant Committee and the Board of Registered Nursing to evaluate specific issues regarding the use of lasers. Specifically, Business and Professions Code Section 2023 states:

*(a) The board, in conjunction with Board of Registered Nursing, and in consultation with the Physician Assistant Committee and professionals in the field, shall review issues and problems surrounding the use of laser or intense light pulse devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants. The review shall include, but need not be limited to, all of the following:*

*(1) The appropriate level of physician supervision needed.*

*(2) The appropriate level of training to ensure competency.*

*(3) Guidelines for standardized procedures and protocols that address, at a minimum, all of the following:*

*(A) Patient selection.*

*(B) Patient education, instruction, and informed consent.*

*(C) Use of topical agents.*

*(D) Procedures to be followed in the event of complications or side effects from the treatment.*

*(E) Procedures governing emergency and urgent care situations.*

*(b) On or before January 1, 2009, the board and the Board of Registered Nursing shall promulgate regulations to implement changes determined to be necessary with regard to the use of laser or intense pulse light devices for elective cosmetic procedures by physicians and surgeons, nurses, and physician assistants.*

The research staff from the Medical Board of California has prepared a comprehensive background document on the relevant topics. The following provides a perspective on physician assistants and delegated scope of practice, a review of relevant existing law, and policy recommendations. This information is prepared and provided by the American Academy of Physician Assistants (AAPA), the national professional society for physician assistants (PAs). The Academy represents over 63,000 physician assistants in all 50 states and the U.S. territories. AAPA's mission is to provide quality, cost-effective, and accessible health care as well as to support the professional and personal development of PAs.

**History of Physician-PA Team Practice**
The PA profession was created by physicians who believed that doctors could treat more patients, utilize their time and talents more wisely, and provide better care if they worked with assistants who were trained in medicine and practiced with physician supervision. This idea has grown into the health profession known as physician assistants. The visionaries of the PA role were right. A physician can more effectively care for patients when working as part of a physician-PA team. The efficiency of this model has led to its utilization in all medical and surgical specialties. The physician-PA team is effective because of the similarities in physician and PA training, the PA profession's commitment to practice with physician supervision, and the efficiencies created by utilizing the strengths of each professional in the clinical workplace.

Physician assistants, working as members of physician-directed teams, now participate in the care of patients from the neonatal intensive care unit to long-term care facilities. As PAs have become well known, many specialist physicians have realized that physician assistants can help extend care to patients in almost every medical and surgical setting. What has not changed is the PA profession's commitment to team practice, with the physician as the captain of the team. Since the inception of the profession, this has remained a constant. PAs are now found in many settings, but the role they play in physician-directed care is identical to the vision of the physicians who created the profession.

**Physician Assistants and Physician Supervision**
The PA profession remains committed to the concept of the supervising physician-PA team. This is reflected in the AAPA's description of the profession:

> *Physician assistants are health professionals licensed or, in the case of those employed by the federal government, credentialed, to practice medicine with physician supervision.*[i]

The commitment to practicing as part of a physician-directed team is clearly stated in the AAPA policy on team practice:

> *The AAPA believes that the physician-PA team relationship is fundamental to the PA profession and enhances the delivery of high quality health care. As the structure of the health care system changes, it is critical that this essential relationship be preserved and strengthened.*[ii]

**Physician Delegated Scope of Practice**
Physician assistants seek and embrace a physician delegated scope of practice. This is unique. No other health profession sees itself as entirely complementary to the care provided by physicians. PAs have great respect for the depth of training received by physicians and acknowledge physicians as the best-educated and most comprehensive providers on the health care team.

Allowing a supervising physician to determine the specific elements of a PA's scope of practice allows for flexible and customized team deployment. The physician has the ability to personally observe the physician assistant's competency and performance and to assure that the PA is performing tasks and procedures in the manner preferred by the supervising physician. The physician also is in the best position to assess the acuity of patient problems seen in a particular setting. The supervising physician is able to plan for PA utilization in a manner that is consistent

with the PA's abilities, the physician's delegatory style, and the needs of the patients seen in the practice.

**Current California Law Governing PA Practice:**
**Requirements for Supervision and Delegation**

The statute and regulations that govern PA practice in California require supervision by licensed physicians (M.D.s or D.O.s). The physician is required to both supervise the PA, and to accept responsibility for care provided. The physical presence of the supervising physician is not required so long as the physician is readily available via telecommunication. The physician is required to assure the PA's competency to perform any procedure prior to delegating it to the PA. The relevant regulation states:

> *1399.545. Supervision Required.*
> *(a) A supervising physician shall be available in person or by electronic communication at all times when the physician assistant is caring for patients.*
>
> *(b) A supervising physician shall delegate to a physician assistant only those tasks and procedures consistent with the supervising physician's specialty or usual and customary practice and with the patient's health and condition.*
>
> *(c) A supervising physician shall observe or review evidence of the physician assistant's performance of all tasks and procedures to be delegated to the physician assistant until assured of competency.*
>
> *(d) The physician assistant and the supervising physician shall establish in writing transport and back-up procedures for the immediate care of patients who are in need of emergency care beyond the physician assistant's scope of practice for such times when a supervising physician is not on the premises.*
>
> *(e) A physician assistant and his or her supervising physician shall establish in writing guidelines for the adequate supervision of the physician assistant which shall include one or more of the following mechanisms:*
>
> *(1) Examination of the patient by a supervising physician the same day as care is given by the physician assistant;*
>
> *(2) Countersignature and dating of all medical records written by the physician assistant within thirty (30) days that the care was given by the physician assistant;*
>
> *(3) The supervising physician may adopt protocols to govern the performance of a physician assistant for some or all tasks. The minimum content for a protocol governing diagnosis and management as referred to in this section shall include the presence or absence of symptoms, signs, and other data necessary to establish a diagnosis or assessment, any appropriate tests or studies to order, drugs to recommend to the patient, and education to be given the patient. For protocols governing procedures, the protocol shall state the information to be given the patient, the nature of the consent to be obtained from the patient, the preparation and technique of the procedure, and the follow-up care. Protocols shall be developed by the physician, adopted from, or referenced to, texts or other sources. Protocols shall be signed and dated by the*

*supervising physician and the physician assistant. The supervising physician shall review, countersign, and date a minimum of 10% sample of medical records of patients treated by the physician assistant functioning under these protocols within thirty (30) days. The physician shall select for review those cases which by diagnosis, problem, treatment or procedure represent, in his or her judgment, the most significant risk to the patient;*

*(4) Other mechanisms approved in advance by the committee.*

*(f) In the case of a physician assistant operating under interim approval, the supervising physician shall review, sign and date the medical record of all patients cared for by that physician assistant within seven (7) days if the physician was on the premises when the physician assistant diagnosed or treated the patient. If the physician was not on the premises at that time, he or she shall review, sign and date such medical records within 48 hours of the time the medical services were provided.*

*(g) The supervising physician has continuing responsibility to follow the progress of the patient and to make sure that the physician assistant does not function autonomously. The supervising physician shall be responsible for all medical services provided by a physician assistant under his or her supervision.*

**Issues Surrounding the Use of Lasers and Similar Devices**

The development of laser technology has created a set of regulatory dilemmas. Although the state of California has determined that lasers may only be used by physicians, nurses and PAs practicing with physician supervision, in other parts of the country lasers are currently used outside medical settings by persons with and without health professional licenses. They are utilized to alter human skin by operators who practice with and without physician supervision. The use of laser and other similar technology currently blurs the line between medicine and cosmetology.

The Academy recognizes the wide range of issues that will be considered by the Boards and the PA Committee in meeting the requirements SB 1423 of 2006. We will confine our comments to the utilization of lasers by physician-PA teams.

**Relevance of Existing Laws to Lasers and Related Technology**

The Academy acknowledges that the study group may recommend that the utilization of lasers and related technology by any professional requires supervision, evaluation, and delegation by a physician. Any practice by a physician assistant requires that a supervising physician delegate, supervise, and take responsibility for care provided by a physician assistant, so effective safeguards **are already required by law for physician assistants.** California regulations authorize a supervising physician to determine a PA's scope of practice via evaluation and delegation, supervise the care provided by the PA, and control quality. We recommend that no additional regulations be imposed for use of lasers and related technology by physician-PA teams.

**<u>Laser Regulation in Other States</u>**

As of mid-2007, 29 states have enacted laws, regulations, or Medical Board policies on the use of lasers. Many of these define the use of lasers on human tissue as the practice of medicine, restricting laser procedures to physicians and those to whom physicians may delegate medical

tasks. Some states make a distinction between ablative and non-ablative applications of laser light, or between laser hair removal and other procedures. Although they vary in the details, all state laser regulations seek to uphold the standard of care by requiring adequate training and supervision of those using lasers.

Among state laser regulations, there is ample precedent for using existing scope of practice and supervision requirements for physician assistants. Several states have acknowleded the special role of PAs when they developed rules on laser use:

**Michigan**
*Sec. 16276.*
1) A licensee, registrant, or other individual shall not perform any procedure using a laser for dermatological purposes unless the procedure is performed under the supervision of a licensed physician.
(2) A licensee, registrant, or other individual shall not perform any procedure using a laser for dermatological purposes unless the patient has knowledge and consents to the procedure being performed by that licensee, registrant, or individual.
(3) Subsection (1) does not apply to any of the following:
(a) A licensed physician.
(b) A licensed physician's assistant who performs such a procedure in a health care facility.
(c) A certified nurse practitioner who performs such a procedure in a health care facility.
(4) The department may promulgate rules to further prohibit or otherwise restrict the use of lasers for dermatological purposes.[iii]

**North Carolina**
*North Carolina Medical Board Position Statement, amended July 2005*
It is the position of the North Carolina Medical Board that the revision, destruction, incision, or other structural alteration of human tissue using laser technology is surgery. Laser surgery should be performed only by a physician or by a licensed health care practitioner working within his or her professional scope of practice and with appropriate medical training functioning under the supervision ... of a physician or by those categories of practitioners currently licensed by this state to perform surgical services.

It is the position of the Board that good medical practice requires that each patient be examined by a physician, physician assistant or nurse practitioner licensed or approved by this Board prior to receiving the first laser hair removal treatment and at other times as medically indicated.

**Rhode Island**
In short, this policy statement defines office-based esthetic procedures including, laser hair removal and Botox injections, as *the practice of medicine*. As such these procedures should only be done by physicians or advanced practice clinicians [e.g. nurse practitioners and physician assistants]; or under the supervision of physicians or advanced practice clinicians. It must be emphasized that medical equipment such as medical lasers and prescription pharmaceuticals should only be purchased by and used under the direction of a physician or advanced practice clinician.[iv]

**Texas**
*193.11(c) Use of lasers in the practice of medicine.*

(2) The use of lasers/pulsed light devices for non-ablative procedures cannot be delegated to non-physician delegates, other than an advanced health practitioner, without the delegating/supervising physician being on-site and immediately available.

Advanced health practitioner" is defined in 193.11(b) as "a physician assistant or an advanced practice nurse."

**Washington**

*Washington Administrative Code, 246-918-125*

(5) A physician assistant may use an LLRP [laser, light, radiofrequency, and plasma] device so long as it is with the consent of the sponsoring or supervising physician, it is in compliance with the practice arrangement plan approved by the commission, and it is in accordance with standard medical practice.

**Actions Proposed by the Medical Board of California's Background Document**

In its May 30, 2007 background document the Medical Board of California proposes that four actions, at minimum, are required. We would like to comment on each in turn.

*Public Forums*

We believe that public dialog on issues is a key part of comprehensive professional regulation. We appreciate the development of the forums and the opportunity to provide input.

*Enforcement strategy*

As noted in the MBC staff's memo, many concerns over the use of lasers and related devices are addressed in existing law. Enforcement of current laws and regulations governing the practice of medicine and corporate involvement in medical care is essential. We concur that a strategy for enforcement of existing law is appropriate.

*Public outreach and education*

As with any evolving issue, education of the public and of licensees is critical. We would endorse this proposed action

*Report to Legislature*

The new statute requires that a report to the legislature be made by January, 2009. If additional legislation is to be considered, we would strongly recommend that the boards and PA Committee evaluate the nature of the perceived problem and craft legislation that targets specific concerns.

**Conclusion**

The American Academy of Physician Assistants is committed to the concept that PAs provide health care as delegated and supervised by a licensed physician. The utilization of lasers and related technology is covered by delegation and supervision requirements already in California law and regulations. Current language offers excellent physician oversight and public protection as it relates to physician-PA teams. Additional regulation of physician assistants for specific technologies is not required.

[i] American Academy of Physician Assistants. 2007-2008 Policy Manual. Alexandria, VA.
[ii] Ibid
[iii] Michigan Compiled Laws 333.16276
[iv] Rhode Island Division of Health Services Regulation policy, adopted 2/12/04
[v] Texas State Board of Medical Examiners regulations, 193.11 (use of lasers)

# California Academy of Physician Assistants

3100 West Warner Avenue, Suite 3, Santa Ana, CA 92704 • Phone: (714) 427-0321 • Fax: (714) 427-0324


WRITTEN TESTIMONY OF JENNIFER A. FAGGIONATO, PA-C
IMMEDIATE PAST PRESIDENT – CALIFORNIA ACADEMY OF PHYSICIAN ASSISTANTS
MEDICAL BOARD OF CALIFORNIA AND BOARD OF REGISTERED NURSING
FORUM ON PUBLIC SAFETY AND THE USE OF LASERS FOR COSMETIC PROCEDURES
THURSDAY, AUGUST 30, 2007

On behalf of the California Academy of Physician Assistants (CAPA) and our nearly 3,000 members, thank you for this unique opportunity to address both the Medical Board of California (MBC) and Board of Registered Nursing (BRN) on this important topic of patient safety and the appropriate use of lasers for cosmetic procedures.

As a physician assistant with clinical experience in emergency medicine, dermatology and plastic surgery, I can certainly attest to need for consumer protection in all facets of medical care. Healthcare consumers need to understand the fundamentals of preventative medicine whether it be simply wearing a bicycle helmet, fastening a seat belt or ensuring that their healthcare provider is clinically capable of performing safe and effective cosmetic laser procedures.

The foundations of physician assistant practice are deeply rooted in clinically appropriate physician supervision. As a matter of policy, CAPA has never strayed from this fundamental tenant. Physician assistants are an integral part of the healthcare team approach across all modes of practice and medical specialties.

However, CAPA believes that the physician assistant and supervising physician relationship is just as strong of a covenant as that, which we have with our patients. To that end, and notwithstanding existing law, CAPA has a long-standing commitment to ensure that the supervising physician determine what medical services shall be delegated to their physician assistant and the method and manner by which that supervision shall occur.

The MBC and Physician Assistant Committee (PAC), a subsidiary of the MBC, already have all the necessary authority to protect the public when clinical judgment of a supervising physician has put patients in harms way. Delegated cosmetic laser procedures performed by a physician assistant need not be treated any differently than any other delegated medical procedure.

CAPA was acutely engaged throughout the legislative process on SB 1432 (Figueroa) – Chapter 873 of 2006. This bill went through four completely different amended versions in a six-month period. This is almost unheard of even by Sacramento standards. CAPA provided technical assistance on SB 1423 and consistently pointed to the Physician Assistant Practice Act and subsequent regulations as the model to address the issue of appropriate physician supervision.

The various stakeholder meetings CAPA participated in regarding SB 1423 has lead us to these public forums on how best to protect the public when receiving cosmetic laser procedures. Therefore, we will remain engaged and committed to protecting the consumer in the most clinically appropriate and medically efficacious manner possible.

Again, thank you for your time and the opportunity.

American Academy of Physician Assistants
950 North Washington Street ■ Alexandria, VA 22314-1552 ■ 703/836-2272 Fax 703/684-1924

**Testimony Presented by Ann Davis, PA-C, Director of State Government Affairs**
**American Academy of Physician Assistants**
**Medical Board of California and Board of Registered Nursing**
**Forum on Public Safety and the Use of Lasers for Cosmetic Procedures**
**Thursday, August 30, 2007**

Good morning. My name is Ann Davis. I am the director of state government affairs for the American Academy of Physician Assistants and a physician assistant licensed in California. The Academy is the national professional society for physician assistants, representing over 63,000 PAs. The Academy appreciates this opportunity to address the Boards on the issue of safe and appropriate use of lasers for cosmetic procedures.

By way of introduction of the testimony, I'd like to quickly review the basic tenants of the physician assistant profession. Let's start with the professional title. The first word in the title of our profession is "physician." That's important. PAs practice as members of a supervising physician's team. PAs recognize physicians as the most comprehensively trained members of the health care team. Those physicians who created the PA profession envisioned a health care professional, trained in the medical model, who would derive their scope of practice from physician delegation and extend the physiican's ability to care for patients.

Forty years into the history of the PA profession these basic tenants are the same. PAs practice with physician supervision and derive their scope of practice by delegation from licensed physicians. This is unique, and I would invite the panel to hold that in mind as they deliberate on this issue.

How are the concepts describing physician-PA practice described in current law? The California PA regulations, which are very similar to those in states across the country, impose these requirements:

- PAs must practice with supervision of a licensed physician who must be available either in person or via telecommunication at all times when the PA is providing patient care
- the physician may delegate only those tasks and procedures consistent with the supervising physician's specialty, or usual and customary practice and with the patient's health an condition
- the physician must observe or review evidence of the PAs performance of all delegated tasks to assure the PA's competency
- The PA and supervising physician must establish transport and back-up procedures for the immediate care of patients who need emergency care when the physician is not on site
- The PA and supervising physician must establish guidelines for adequate supervision of the PA. This may include same day examination by the physician or protocols
- The supervising physician has continuing responsibility to follow the progress of the patient and to assure that the PA practices with supervision. The physician is responsible for all services provided by the PA

PAs are also required to clearly identify themselves and their professional title. In addition, the medical practice includes "false or misleading advertising" as grounds for discipline.

These regulatory provisions governing physician-PA practice are remarkably similar to the concepts set forth in Senator Figueroa's legislation and to the agenda of the committee. Regarding laser use for cosmetic treatment, the bill and the committee seek to address physician supervision, training and competence, procedures and protocols, the handling of emergency situations, ongoing responsibility for care, ultimate responsibility and liability, identification of the service provider and appropriate representation of services.

In short, the safeguards required for appropriate use of lasers in cosmetic procedures are already in place for physician assistants.

To put the issue in perspective, there is new technology all around us. The laws governing physician-PA teams address this by imposing requirements for supervision, delegation, physician oversight and responsibility that apply in all clinical situations. We believe that they are more than adequate to address the issue of laser use in cosmetic treatment.

There is ample precedent for using existing scope of practice and supervision requirements for physician assistants in other states. Several states have acknowledged the special role of PAs when they developed rules or board opinions on laser use:

**Michigan**
*Sec. 16276.*
1) A licensee, registrant, or other individual shall not perform any procedure using a laser for dermatological purposes unless the procedure is performed under the supervision of a licensed physician.
(2) A licensee, registrant, or other individual shall not perform any procedure using a laser for dermatological purposes unless the patient has knowledge and consents to the procedure being performed by that licensee, registrant, or individual.
(3) Subsection (1) does not apply to any of the following:
(a) A licensed physician.
(b) A licensed physician's assistant who performs such a procedure in a health care facility.
(c) A certified nurse practitioner who performs such a procedure in a health care facility.
(4) The department may promulgate rules to further prohibit or otherwise restrict the use of lasers for dermatological purposes.

**North Carolina**
*North Carolina Medical Board Position Statement, amended July 2005*
It is the position of the North Carolina Medical Board that the revision, destruction, incision, or other structural alteration of human tissue using laser technology is surgery. Laser surgery should be performed only by a physician or by a licensed health care practitioner working within his or her professional scope of practice and with appropriate medical training functioning under the supervision ... of a physician or by those categories of practitioners currently licensed by this state to perform surgical services.

It is the position of the Board that good medical practice requires that each patient be examined by a physician, physician assistant or nurse practitioner licensed or approved by this Board prior to receiving the first laser hair removal treatment and at other times as medically indicated.

**Rhode Island**
In short, this policy statement defines office-based esthetic procedures including, laser hair removal and Botox injections, as *the practice of medicine*. As such these procedures should only be done by physicians or advanced practice clinicians [e.g. nurse practitioners and physician assistants]; or under the supervision of physicians or advanced practice clinicians. It must be emphasized that medical equipment such as medical lasers and prescription pharmaceuticals should only be purchased by and used under the direction of a physician or advanced practice clinician.

**Texas**
*193.11(c) Use of lasers in the practice of medicine.*
(2) The use of lasers/pulsed light devices for non-ablative procedures cannot be delegated to non-physician delegates, other than an advanced health practitioner, without the delegating/supervising physician being on-site and immediately available.

Advanced health practitioner" is defined in 193.11(b) as "a physician assistant or an advanced practice nurse.

**Washington**
*Washington Administrative Code, 246-918-125*
(5) A physician assistant may use an LLRP [laser, light, radiofrequency, and plasma] device so long as it is with the consent of the sponsoring or supervising physician, it is in compliance with the practice arrangement plan approved by the commission, and it is in accordance with standard medical practice.

The Academy appreciates this opportunity to provide this information and would be happy to provide additional information upon request.

Society of Dermatology
Physician Assistants

WRITTEN TESTIMONY OF ROBERT C. HIGHAM, MPAS, PA-C
PRESIDENT – SOCIETY OF DERMATOLOGY PHYSICIAN ASSISTANTS
MEDICAL BOARD OF CALIFORNIA AND BOARD OF REGISTERED NURSING
FORUM ON PUBLIC SAFETY AND THE USE OF LASERS FOR COSMETIC PROCEDURES
THURSDAY, AUGUST 30, 2007

My name is Robert C. Higham, MPAS, PA-C and I am a physician assistant (PA) practicing full time in dermatology since 1999. I am also the President of the Society of Dermatology Physician Assistants (SDPA). The SDPA represents over 1200 PAs throughout the nation and is the professional organization that represents PAs in dermatology. I currently work with a Board Certified Dermatologist, Allan S. Wirtzer, MD in Sherman Oaks California.

I first want to apologize for not being able to be present with you today to give my testimony in person however SB 1423 is of great concern to me personally and for the SDPA members I represent. I want to give you some "real life" examples of how I use lasers on a daily basis and how my "physician-PA team" works together to provide this care safely and effectively for many years.

The use of Lasers and light based technology in dermatology is expanding very quickly and can be used in both medical cases as well as cosmetic cases. When I started in dermatology we had a total of one laser in our practice. It was used primarily to treat tattoos and discoloration on the skin. Now, eight years later, our physician-PA team utilize a total of 5 lasers that treat a number of conditions including, psoriasis, vitiligo, eczema, vascular birthmarks, unwanted or superficial veins, precancerous growths along with the multiple cosmetic conditions including unwanted hair, sun damaged skin and resurfacing techniques.

Limiting the times or conditions in which PAs may utilize one of these lasers will affect patients conditions and quality of life significantly. Unlike common belief, all lasers do not only treat cosmetic conditions. There will be instances that my supervising physician will be away from the office at a meeting, out due to illness or on vacation but available by electronic means. If the physician-PA team is limited in the use of lasers by not being allowed to treat a patient because my supervising physician is out of the office seems to harm more than help patients. Many of the conditions we use the lasers for require two to three treatments per week to be successful, vitiligo and psoriasis to name a few. If a patent needed to be interrupted in their treatment cycle there quality of life will be affected.

Lasers can be a very dangerous in the wrong persons hand. We have all heard and seen some of the "horror" stories that can occur because of inappropriate and unsupervised use of lasers. We are here today discussing this issue because of situations like these which have unfortunately occurred. PAs are unique in medicine, we work as delegates of the supervising physicians. That is, that my physician must determine that I have met the educational, training and proficiency testing for him to delegate to me the use of lasers in my delegation of services agreement. If I am not competent and proficient in the use of lasers then I would expect him not to

P.O. Box 701461 • San Antonio, Texas 78270 • phone 800-380-2992 • fax 830-438-5425 • www.dermpa.org

Society of Dermatology
Physician Assistants

delegate those duties to me.

It is my opinion and the opinion of the SDPA that supervision decisions should be left up to the individual physician in the clinic who is in the best position to assess the competency and regulate the use of lasers by the PAs he supervises on a daily basis. Current state law for supervision of PAs has the necessary checks and balances PAs need to operate these devices, additional restrictions will only serve to limit medical care to the patients who need it.

In closing I wanted to share with the committee some information from the SDPA 2007 Dermatology PA Workforce Survey. The survey was sent to 1800 PAs working in dermatology earlier this summer and we had just over 600 people complete the survey. Currently, 47% of our members use lasers in their daily practice. In addition 47% meet daily with their supervising physician to discuss cases while 27% meet two to three times a week. 77% of our members work in only one office and of the 23% of PAs that do work in a satellite office the supervising dermatologist is present 44% of the time. Under these real life circumstances physician-PA team do and can continue to operate lasers and light based technologies safely.

Thank you for the opportunity to address the committee.

ASDS
American Society for
Dermatologic Surgery

## THE AMERICAN SOCIETY FOR DERMATOLOGIC SURGERY

**Year founded:** 1970

**Membership:** Nearly 4,700 board-certified dermatologic surgeons worldwide are members.

**About the ASDS:** Dermatologic surgery is one of the most innovative and progressive medical subspecialties in the U.S. American Society for Dermatologic Surgery (ASDS) members are at the forefront of the development of safe, in-office procedures that are saving lives by diagnosing and treating potentially deadly skin cancers earlier and more effectively.

Dermasurgeons have also pioneered breakthrough, minimally invasive treatments to restore vitality to sun-damaged skin, returning it to its healthier, more youthful appearance. The time and commitment invested by dermasurgeons in research and advancement of new technologies have resulted in unprecedented growth and acceptance of cosmetic procedures.

Today, ASDS members are recognized within the medical community as leaders in the field of dermatology and as advocates for patient safety. ASDS members not only lead the field of specialists in the treatment of skin cancer, but also are the premier specialty group trained to treat skin and soft tissue in both medically necessary and cosmetic surgical and non-surgical methods.

**ASDS purpose:** The purposes of the Society shall be to foster, promote, support, augment, develop and encourage investigative knowledge in dermatologic surgery; to promote the highest possible standards in clinical practice, continuing education, and research in dermatologic surgery; to promote the highest standards of patient care and promote the public interest relating to dermatologic surgery; and to provide a forum for the exchange of ideas and methodology for dermatologic surgery and related basic sciences.

5550 Meadowbrook Drive, Suite 120 Rolling Meadows, IL 60008 Tel. 847-956-0900 Fax. 847-956-0999 www.asds.net

ASDS
American Society for
Dermatologic Surgery

# POSITION STATEMENT ON NON-PHYSICIAN USE OF LASERS AND INTENSE PULSED LIGHT DEVICES

1. Physicians shall be trained appropriately in the physics, safety, and surgical techniques using lasers and intense pulsed light devices, as well as pre-and post-operative care. Any physician who delegates a procedure using lasers or intense pulsed light devices to a non-physician must also be qualified to do the procedure themselves by virtue of having received appropriate training in physics, safety, and surgical techniques using lasers and intense pulsed light devices, as well as pre- and post-operative care.

2. Any allied health professional employed by a physician to perform a laser or intense pulsed light procedure must have received appropriate documented training and education in the safe and effective use of each system, be properly licensed in their state, and be adequately insured for that procedure.

3. A properly trained and licensed allied health professional may carry out a specifically designated laser or intense pulsed light procedure only under direct physician supervision following established written procedures which are immediately available for reference at the specific site where the procedure is to be performed.

4. Since the ultimate responsibility for properly performing any procedure lies with the physician, the supervising physician shall be physically present, and immediately available, and able to respond promptly to any question or problem that may occur while the procedure is being performed.

The guiding principle for all dermatologic surgeons is to practice ethical medicine with the highest possible standards to ensure that the best interests and welfare of each patient are guaranteed. The ASDS endorses the concept that use of properly trained and licensed allied health professionals under appropriate direct physician supervision allows certain procedures using lasers or intense pulsed light devices to be performed safely and effectively.

Approved: October 1997
Revised: December 1999

5550 Meadowbrook Drive, Suite 120 Rolling Meadows, IL 60008 Tel. 847-956-0900 Fax. 847-956-0999 www.asds.net

ASDS
American Society for Dermatologic Surgery

# Forum on Public Safety and the Use of Lasers for Cosmetic Procedures

August 30, 2007

# ASDS PATIENT SAFETY SURVEY

- Survey results showed that in the past year:
  - 65% of respondents treated complications caused by a non-physician.
  - 92% of respondents treated patients with skin cancer, some of which resulted in patient mortality, which was either overlooked or misdiagnosed by a non-physician.

ASDS American Society for Dermatologic Surgery

© 2004 American Society for Dermatologic Surgery

# MISDIAGNOSIS

- Patient seen 11 months later by Dermatologist with subcutaneous mass
- Bx diagnosis: "Amelanotic melanoma, locally metastatic"


© 2004 American Society for Dermatologic Surgery

# ASDS PATIENT SAFETY SURVEY

- Over the last two years:
  - 57% of respondents saw an increase in the number of patients they treated as a result of complications caused by a non-physician.
- Over the last five years:
  - 38% of respondents saw a 5% to 25% increase in the numbers of complications they have treated from non-physicians.


© 2004 American Society for Dermatologic Surgery

# ASDS PATIENT SAFETY SURVEY

- The top three complications include:
  - Burns and scarring from laser hair removal
  - Misdiagnosis of skin cancer
  - Burns and scarring from chemical peels


© 2004 American Society for Dermatologic Surgery

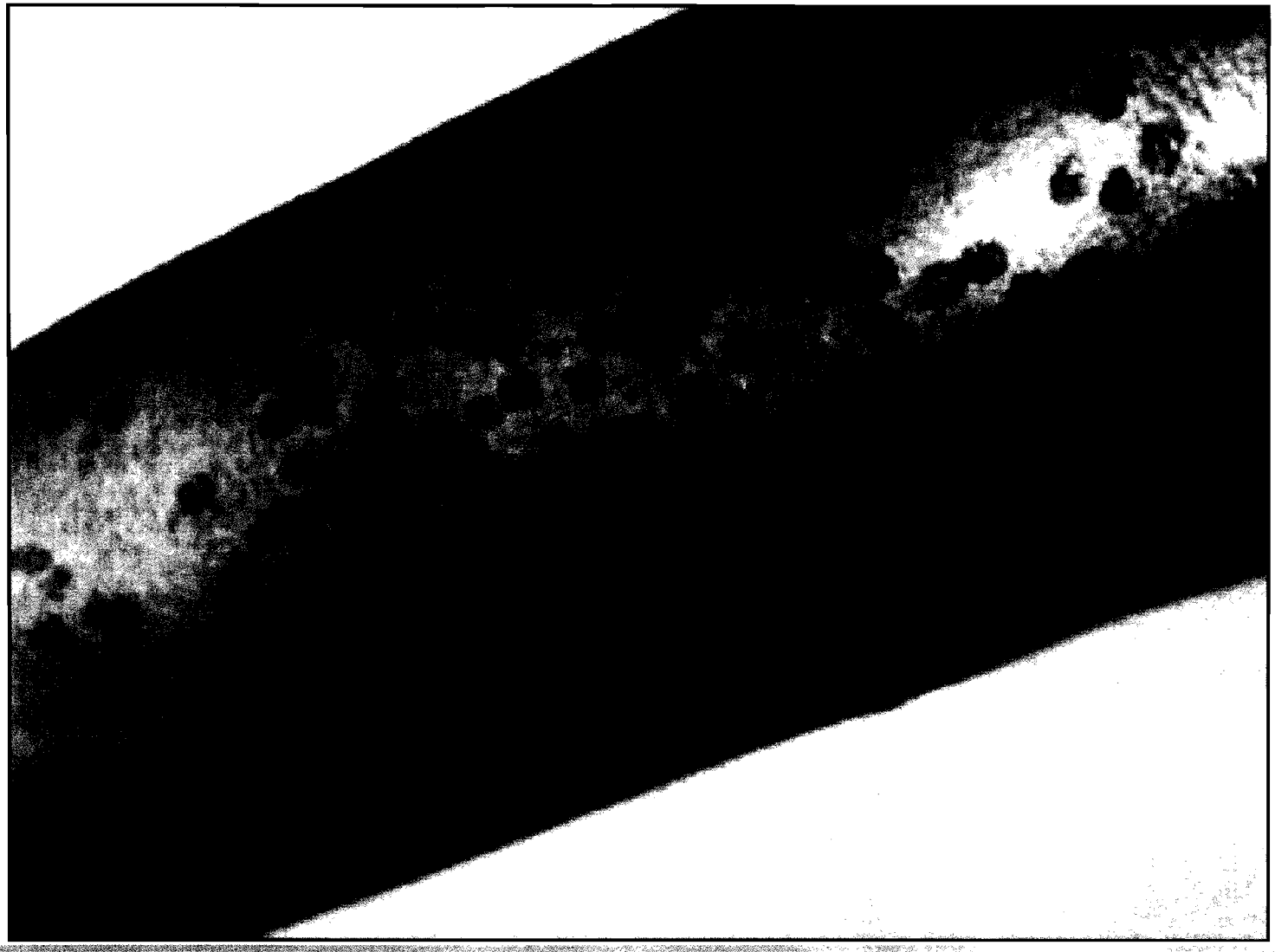
ASDS American Society for Dermatologic Surgery

© 2004 American Society for Dermatologic Surgery

# Laser Hair Removal by a non-physician in a CA mall spa

ASDS American Society for Dermatologic Surgery

© 2004 American Society for Dermatologic Surgery



Hyperpigmentation, hypopigmentation, and scarring on a forearm resulting from the use of a laser by a non-physician for hair removal



© 2004 American Society for Dermatologic Surgery

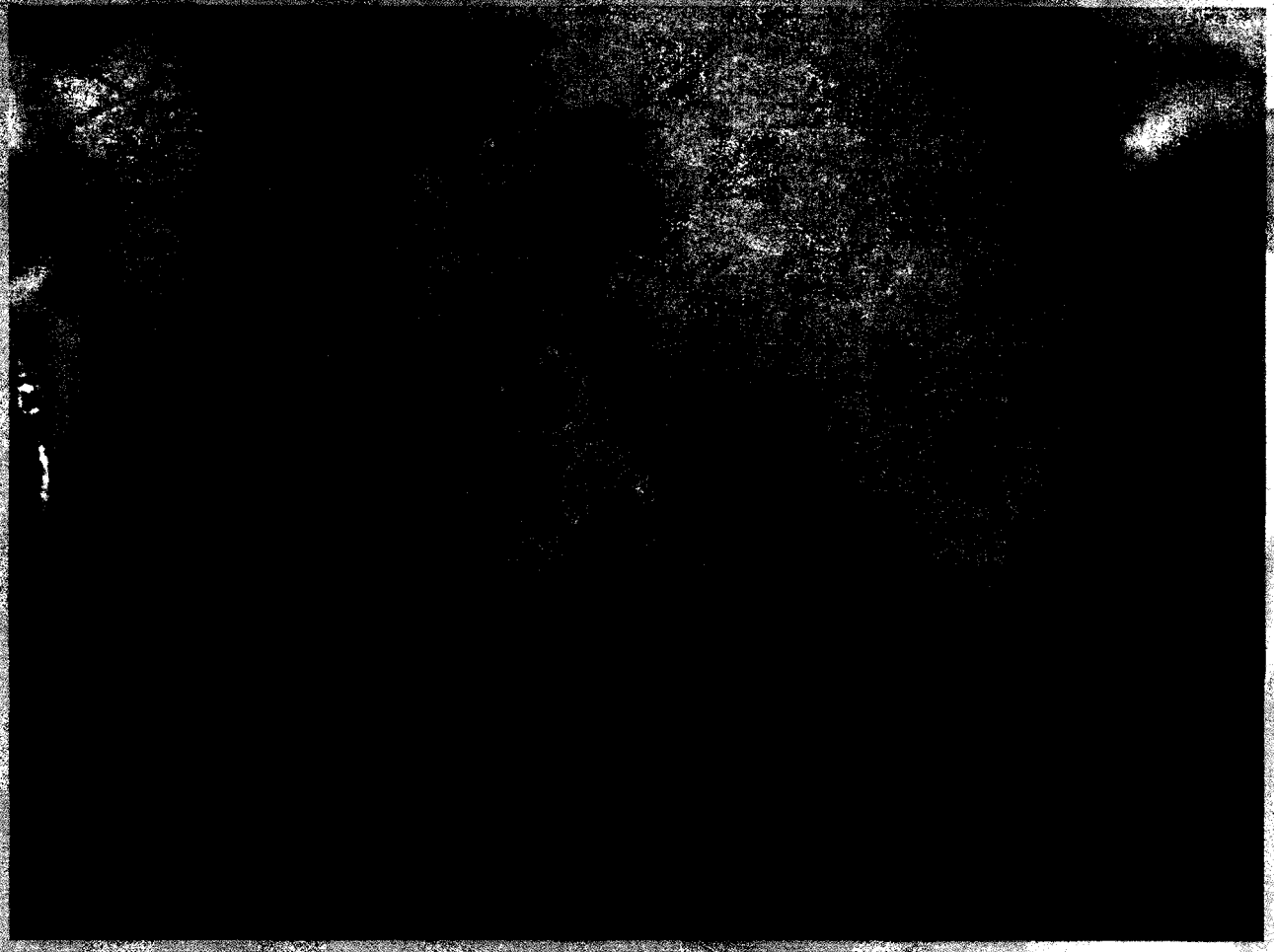
# NON-ABLATIVE LASER

- Burns and scars

ASDS American Society for Dermatologic Surgery

© 2004 American Society for Dermatologic Surgery

# Burns from laser hair removal



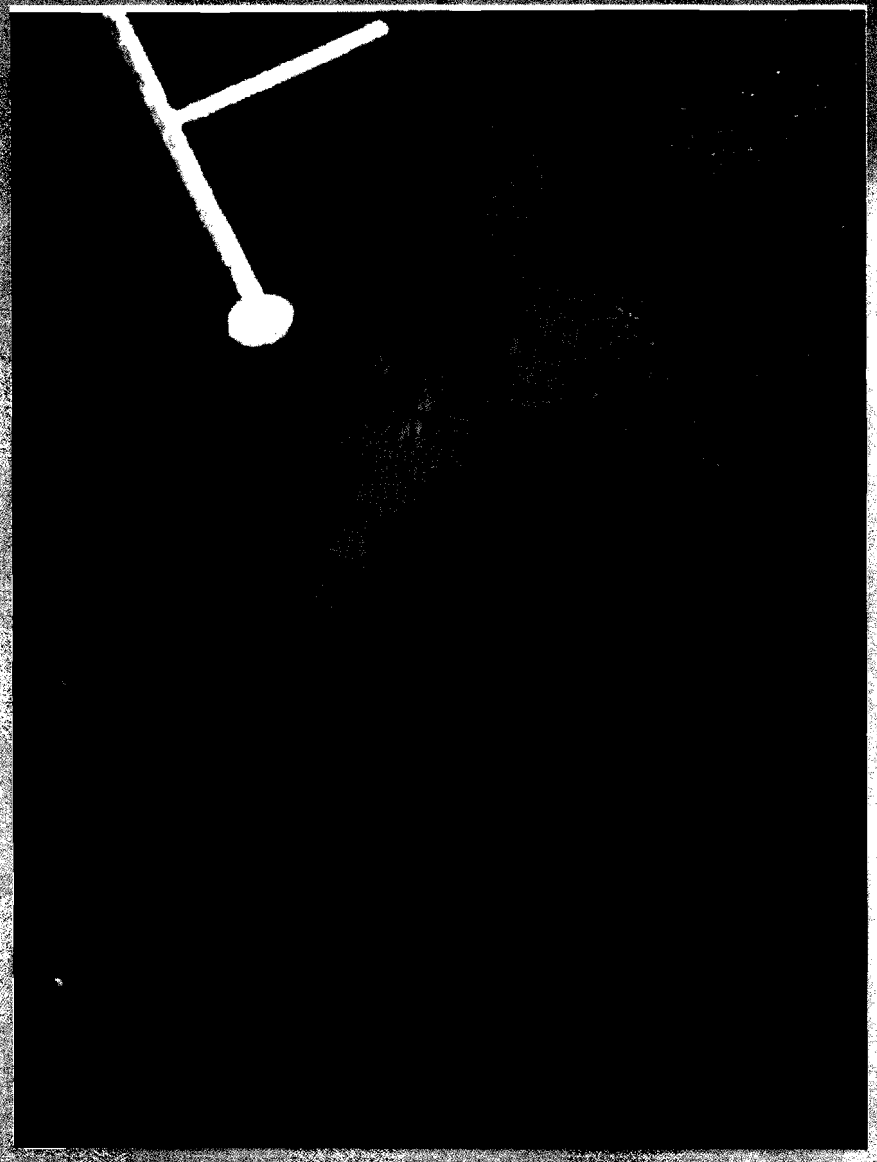
ASDS American Society for Dermatologic Surgery

© 2004 American Society for Dermatologic Surgery

Laser sunspot removal at a medispa

ASDS American Society for Dermatologic Surgery

© 2004 American Society for Dermatologic Surgery



ASDS
American Society for Dermatologic Surgery

© 2004 American Society for Dermatologic Surgery

# FATAL REACTIONS

- **Lidocaine Toxicity**
- 22-year-old female – hair removal treatment at a "Day Spa" in North Carolina. Application of "lidocaine cream" over widespread body surface area with occlusion.
- Non-FDA pharmacy dispensed.
- No physician associated with Spa though medical director – plastic surgeon – named.
- Patient died of lidocaine toxicity.


© 2004 American Society for Dermatologic Surgery

# ASDS POSITION

Non-physicians are not trained to:

- Diagnose skin disease.
- Evaluate the causes, types and symptoms of skin conditions related to aging and sun-damage.
- Therefore, are ill-equipped to treat these skin disorders without direct medical supervision.
- This leads to INACCURATE treatment!


© 2004 American Society for Dermatologic Surgery

# ASDS POSITION

- Under appropriate circumstances, certain cosmetic medical procedures can be delegated.
- But only to trained and licensed medical staff with direct, on-site supervision by a physician.
- On-site physician supervision ensures the necessary responsiveness to questions and hopefully the avoidance of complications as well as treatment of complications should they arise.


© 2004 American Society for Dermatologic Surgery

# STATEMENT OF THE CALIFORNIA SOCIETY OF PLASTIC SURGEONS (CSPS)

## Submitted to the

## MEDICAL BOARD OF CALIFORNIA
## &
## BOARD OF REGISTERED NURSING

## *Forum on Public Safety and the Use of Lasers for Cosmetic Procedures*

## August 30, 2007

The California Society of Plastic Surgeons (CSPS) appreciates the opportunity to comment on the issues relating to the use of lasers and patient safety. The CSPS is committed to ensuring the safety of patients while maintaining their access to quality care.

In your May 30, 2007 memo, you requested comments concerning the following:

- Patient Safety
- Training and Education
- Physician Supervision
- Patient Referrals and Aggressive Advertising Techniques
- Liability
- Technological trends
- Proposed changes to current law, regulation and enforcement

The CSPS respectfully submits the following comments in response to the above request.

**Patient Safety/Training & Education/Physician Supervision**

The American College of Surgeons (ACS) recently issued, in its Vol.92, No. 4, April 2007 Bulletin, a *Statement on surgery using lasers, pulsed light, radiofrequency devices, or other techniques [ST-11]* that includes the following:

*"Recognizing the increased usage of laser surgery and to provide professional guidance to state and federal regulatory bodies addressing laser and other surgery issues, the American College of Surgeons wishes to make the following revised statement regarding these operative techniques. The original statement was published in the March 1991 issue of the Bulletin, and this revised statement was approved by the Board of Regents at its February 2007 meeting.*

*Surgery is performed for the purpose of structurally altering the human body by the incision or destruction of tissues and is a part of the practice of medicine. Surgery is also the diagnostic or therapeutic treatment of conditions or disease processes by any instruments causing localized alteration or transposition of live human tissue, which include lasers, ultrasound, ionizing radiation, scalpels, probes, and needles. The tissue can be cut, burned, vaporized, frozen, sutured, probed, or manipulated by closed reduction for major dislocations and fractures, or otherwise altered by any mechanical, thermal, light-based, electromagnetic, or chemical means. Injection of diagnostic or therapeutic substances into body cavities, internal organs, joints, sensory organs, and the central nervous system is also considered to be surgery (this does not include administration by nursing personnel of some injections, such as subcutaneous, intramuscular, and intravenous when ordered by a physician). All of these surgical procedures are invasive, including those that are performed with lasers, and the risks of any surgical intervention are not eliminated by using a light knife or laser in place of a metal knife or scalpel.*

*In recent years, technological advances have made it possible to perform cosmetic surgical procedures of the skin using a variety of devices and techniques. Lasers, pulsed light, and radiofrequency devices are often used for ablative and nonablative treatments. An ablative treatment is expected to excise, burn, or vaporize the skin below the dermo-epidermal junction. Nonablative treatments are those that are not expected or intended to excise, burn, or vaporize the epidermal surface of the skin. Any procedures that can damage the eye (cornea to retina) are ablative and should only be performed by a licensed physician.*

*The American College of Surgeons believes that surgery using lasers, pulsed light, radiofrequency devices, or other means is part of the practice of medicine and constitutes standard forms of surgical intervention. It is subject to the same regulations that govern the performance of all surgical procedures, including those that are ablative or nonablative, regardless of site of service (that is, hospital, ambulatory surgery center, physician's office, or other locations). Patient safety and quality of care are paramount, and the College therefore believes that patients should be assured that individuals who perform these types of surgery are licensed physicians (defined as doctors of medicine or osteopathy) who meet appropriate professional standards. This is evidenced by comprehensive surgical training and experience, including the management of complications, and the acquisition and maintenance of credentials in the appropriate surgical specialties (that is, board certification) and in the use of lasers, pulsed light, radiofrequency devices, or other similar techniques.*

*However, the College also recognizes that the use of ablative lasers may be delegated to non-physician advanced health care practitioners (defined as nurse practitioners or physician assistants) who are appropriately trained and licensed by the state in which they practice. Ablative treatments or procedures performed by nonphysician advanced health care practitioners should fall within the statutory and/or regulatory scope of the practitioner's profession. The physician may delegate the performance of ablative*

*treatments through the use of written protocols to an advanced health care practitioner. Direct supervision should be provided by the physician whenever performance of ablative treatments has been delegated to an advanced health practitioner, unless specific state regulations allow for lesser amounts of supervision. The physician is responsible for doing the initial review of the patient and for authorizing the treatment plan. This should be appropriately noted in the patient's chart prior to any initial ablative treatment.*

*In those cases where the surgeon may utilize the services of a nonphysician advanced health practitioner or nonphysician health practitioner as an assistant during the performance of laser surgery (including ablative or nonablative procedures), the assistant must meet the following requirements:*

** Be properly licensed, certified, and/or credentialed to practice his or her profession*
** Have appropriate education and training for assisting the surgeon in laser surgery procedures*
** Complete assigned duties under the direct supervision of the surgeon performing the procedure*

*Individuals who perform laser surgery utilizing lasers, pulsed light, radiofrequency devices, or other techniques should meet the principles of the College in all respects (see http://www.facs.org/fellows_info/statements/stonprin.html), to include the avoidance of any misrepresentations to the public regarding unfounded advantages of the laser compared with traditional operative techniques."*

---

The CSPS agrees with the American College of Surgeons that the use of lasers, pulsed light, radiofrequency devices, or other means of altering the skin does constitute the practice of medicine. Use of such devices should be limited to physicians or to the appropriately trained registered nurses/physician's assistants under their supervision and using standardized protocols and procedures. An integral part of the standardized policies and procedures is a well-documented quality assurance (QA) program that may contain quarterly or monthly QA meetings to discuss patient complications and issues, as well as follow-up and management of the issues until resolved and what has been done to prevent their subsequent reoccurrence.

The BRN, in its September 1999 *Performance of Laser Therapy by RNs* document, stated that,

> *"The RN must receive appropriate education and supervised practice to ensure competency in performing the laser therapies, must be able respond appropriately to complications, and must be able to respond to untoward effects of laser procedures. In addition to procedural and clinical aspects of laser technology and treatment, appropriate education should include didactic and clinical experience related to laser technologies for medical purposes, including laser safety standards."*

Training of registered nurses/physician's assistants may be provided by regional or national medical organizations, as well as by the device manufacturers. A separate license to use said devices is unnecessary as long as the appropriate education and training of the provider is documented. The supervising physician must also have completed the same education and training, in order to adequately supervise these physician extenders.

The supervising physician must be available on-site or by telephone. The supervising physician must be available for a face-to-face examination of the patient, should a complication arise, within 24 hours.

**Marketing and Liability Issues**

It is shameful that in much of the marketing for medical-spa procedures, it is difficult to discern who will actually be performing the treatments. The CSPS is a vigorous proponent of truth in medical advertising. The Medical Board of California and the Board of Registered Nursing must be vigilant in the regulation of advertising. We believe that all advertising must list the supervising physician, as well as who would actually be performing the procedures.

The CSPS is aware of several instances where independent registered nurses have set themselves up in business running 'laser spas', treating patients with little or no physician oversight. Sometimes the "supervising physician" is provided a kick-back or other unlawful financial incentive for the use of their "name". There have been incidents of medical-spa companies recruiting physicians to be "clinic directors" who are paid for their services, even though they are never on-site and have never seen any of the patients. The MBC must actively enforce current law that prohibits payment for patient referral and other fee-splitting arrangements.

Any supervising physician must assure they have adequate medical malpractice coverage for this activity. The CSPS is aware of instances where medical malpractice carriers refuse to issue liability coverage to physicians acting as "directors" of medical-spas that are actually run by registered nurses. In all instances, patients have the right to know exactly who the medical director of the facility is, how they can be contacted, and who is ultimately responsible for the treatment that they are receiving.

**In Closing**

We look forward to working with the Medical Board of California (MBC) and the Board of Registered Nursing (BRN) through this forum and welcome the opportunity for an ongoing dialogue with you on these important patient safety issues.

CSPS Executive Office
3664 San Pablo Dam Road
El Sobrante, CA 94803
PH: (510) 243-1662 FAX: (510) 243-1663
Email: cpahl@earthlink.net

# Use of Lasers for Cosmetic Procedures
# MBC Hearing
# August 30, 2007

*James Newman, MD, FACS*

*California Society of Facial Plastic Surgery*

# CSFPS

- *California Society of Facial Plastic Surgery*
- *10 Year Anniversary subspecialty delegate CMA*
- *Promote and Foster Excellence in Facial Plastic Surgery*
- *Educate Public about Facial Plastic Surgery Training and Expertise*
- *Promote Safety and Standards for FPS*
- *200 Members throughout CA abide by Code of Ethics with American College of Surgeons and the American Academy of FPRS*

# Recognizing the Problem

- *Patients are being treated by entities unlawfully engaged in the practice of medicine*
- *Adequate Laws exist protecting patients against the Corporate Practice of Medicine*
- *Pseudo MediSpas are in business to profit financially from medical procedures without diagnosis, treatment plans, and follow ups*
- *Sites are run unsupervised with "ghost physician" medical directors*
- *100% of CSFPS members polled March 2007 Educational Forum Lake Tahoe, CA reported at least one entity in their community where unsupervised treatments were being performed generating numerous patient complaints*

# Key Issues to Promote Safety

- *Awareness of Consumer that some services are Medical Procedures*
- *Higher Standards for Medical Directors*
- *Focus on Core Specialty Physicians*
- *Success in supervision of RN and PA*
- *Why Corporate Practice of Medicine hurts Consumers*
- *Recommendations from CSFPS*

# Medispa Patient Safety

- *When does a CONSUMER become a PATIENT in a MediSpa?*
- *Are properly trained physician's performing and or supervising procedures?*
- *Are physicians properly supervising licensed nurses and PA's within their practice?*
- *What is the setting in which these treatments are being performed?*
- *Are patient's being treated under an unlawful Corporate Practice of Medicine?*

# From Consumer to Patient

- *The explosion of medispas has blurred the distinction for people coming in for a personal service at a spa vs. a medical service.*
- *A consumer receives a personal service such as that performed by a licensed cosmetologist or aesthetician and is protected based on the scope of practice and license for those services.*
- *When a medical procedure is contemplated, a Physician should be the one consulted and supervise the treatments.*
- *When a medical procedure is contemplated, the Consumer now becomes a PATIENT and the rules of the Practice of Medicine should apply.*

# Medispa Problems

- *Physicians employed to be a medical director do not supervise the staff at the spas and do not control the high rates of turnovers seen at these centers.*
- *80% (24 of 30 patients) polled in San Mateo County treated at a MediSpa reported being treated by different individuals during their repeat visits for laser hair removal and never saw the physician.*

# Consumers are the Losers

- *When these entities close, patients have no one to follow up with, loose prepaid services, have no recourse*
- *ex. Forever 17 in Burlingame operated for 14 months, Laser Hair Clinic in San Mateo operated for 18 months, Radiance Skin Clinic in Menlo Park operated for 18 months*
- *No medical records available, no one to finish treatments, patients could not track down nurses who performed the procedures, most never met the medical director*

# Case example

- *MC was treated at a local Medispa for Laser Hair Removal. Never saw the MD, on her second Rx by a different RN she felt burned. Was told she had a herpetic outbreak over the phone. Never saw the MD.*
- *She came to our office for a 2nd opinion*

# May 5, 2007

- *Full Thickness 3rd degree burn*
- *Will need ongoing treatment possible scar revision*
- *Technology used was appropriate, settings were ok, but the operator stacked pulses and did not recognize the injury she was creating*

# Its not the Tools, it's the operator

- *No matter how many safety features are put into the technology, avoidable complications will occur because of untrained individuals without supervision*

- *A highly skilled recovery RN who takes care of ill patients cannot be expected to perform laser Rx and injections without new training and supervision*

# Why Core Specialties?

- *Extensive training to diagnose and treat conditions of the skin throughout their residencies and fellowships*
- *Use Lasers and Light Based therapies for a multitude of conditions not just cosmetic*
- *Have adequate training to handle complications, burns, dyschromia, and recognize malignancies and perform biopsies when indicated*
- *Have experience using Botulinum Toxin and fillers during residency for functional impairments, deformities, and reconstruction as well as cosmetic indications*

# What does work--When a consumer becomes a patient.

- *When consumers are informed that they are becoming a patient and their care will be run by physicians practicing medicine with the requisite training and fund of knowledge necessary to diagnose and treat their condition.*
- *Supervision of physician extenders such as RNs and PAs works when the Physician comes from a background of one of the core specialties and is the owner of the entity and is responsible for the patients*

# Why Core Physicians?

- *An adequately trained physician within the core specialties who abides by the ethics codes set forth by their specialty organizations have demonstrated success and safety of physician extenders at their main office as well as satellite offices.*
- *Physicians employed by corporate entities to run medispas often lack the experience and requisite training to diagnose, treat, and handle complications from treatments being performed at these clinics*

# RECOMMENDATIONS

- *Enforce the Laws as currently written regarding the Corporate Practice of Medicine*
- *Higher Standard for Medical Directors of Medispas ---Dermatology, Plastic Surgery, and Facial Plastic Surgery or equivalent training with Ownership and Responsibility*
- *Specialty Core Physicians with requisite training have a good working relationship with RNs and PAs at their main clinic as well as satellite offices for Patient Safety and Satisfaction*

# RECOMMENDATION

- ***Bill of Rights for Consumers wanting to Become Patients at a MEDISPA***
  - ***Consumer is to be informed that they are considering a medical procedure and must be seen and examined by the MD owner or designee and that they are now considered a PATIENT of Dr X.***
  - ***Consumer is to have procedures performed in a clean medical office environment***
  - ***If a Nurse or PA is performing a procedure, the Patient must have already been cleared for the procedure by their MD and that their MD is approving their treatment.***

# Bill of Rights

- *A Patient should not be offered a procedure without an exam and diagnosis given by the MD owner.*
- *Patient is to be informed that their treatment plan and ongoing condition has been reviewed by the MD before continuing with subsequent treatments.*
- *Patient will be seen within a reasonable period of time by the MD for any concerns or possible complications.*
- *Patient will have their medical records maintained and privacy protected as if in a formal medical office.*
- *Patient is to be informed of the MD owner's background training and core specialty designation.*

# Conclusion

- *Enforcement of Laws in Place*
- *Higher Standard for Medical Directors*
- *Patient Bill of Rights at Medispas*